

REMARKS

The Examiner is respectfully requested to enter this Reply After Final in that it raises no new issues. Alternatively, the Examiner is respectfully requested to enter this Reply After Final in that it places the application in better form for Appeal.

Status of the Claims

Claims 13-17 and 20-24 are pending in the above identified application. No claims have been canceled, added or amended. Applicants offer the following arguments in support of the patentability of the claims.

Rejection Maintained Under 35 USC 103(a)

The Examiner rejects claims 13, 14, 16, and 20-23 as obvious over Manolagus in view of Zawatzky et al. Applicants traverse the rejection and respectfully request the withdrawal thereof.

The present invention is directed to a method of treating a patient suffering from an osteoclast related bone disorder comprising administering an effective amount of interferon β or an interferon β induced to reinstate bone volume in the patient.

Distinctions between the Present Invention and Cited Art

Zawatzky discloses negative regulatory effects that IFN- β exerts on the production of IL-6 in very limited conditions. Zawatzky employs virus infection as an experimental condition, where the effect of the IFN- β on IL-6 production as a negative regulator is specifically observed when NDV is used (see the Abstract at lines 4 and 5). However, similar effects are not exactly observed from all viruses (see page 4842, right column, lines 9 to 12). As such, Applicants submit that the disclosure of Zawatzky cannot be said to teach or suggest with a reasonable expectation of success that IFN- β functions as a negative regulator for IL-6 production in the diseases and disorders specifically recited in the present invention. The specifically recited diseases and disorders are not disclosed in Zawatzky and are not related to NDV.

The Examiner attempts to draw a correlation between elevated IL-6 levels with bone resorption as taught in Manolagus and the disclosure of Zawatzky. However, Applicants rely on the arguments submitted in the Reply filed March 18, 2002. The previous arguments are incorporated by reference thereto. One of ordinary skill in the art would not with a reasonable expectation of success expect to use IFN- β as a negative regulator to treat an osteoclast related

bone disorder in a patient from the mere disclosure of Zawatzky. This being the case particularly when several references within the field of art specifically teach that IFN- β is a positive regulator and Zawatzky does not discuss the opposite findings within the reference. As such, Applicants submit that the teachings in Zawatzky are unreliable and are surely not a piece of art that one of ordinary skill in the art would rely on for combining with Manolagus to arrive at the present invention. As such, Applicants submit that there is no motivation to combine the references.

Thus, Applicants submit that the Examiner has failed to make a prima facie case of obviousness as the Examiner has failed to point to the disclosure or suggestion of each and every limitation of the claimed invention within the references or in some general teaching known in the art. As such, Applicants submit that the rejection should be withdrawn as no prima facie case of obviousness has been established.

Rejection under 35 USC 102(b)

The Examiner rejects claims 13, 17, 20 and 22-24 as anticipated by Haase and Lange. Applicants traverse the rejection and respectfully request the withdrawal thereof.

Applicants submit that Haase and Lange merely disclose an antitumoral effect of IFN- β on metastatic osteoncus. Haase and Lange does not disclose the effects of IFN- β on the prevention and treatment of osteoclasia that occurs after metastatic osteoncus. As such, Haase and Lange fail to disclose each and every limitation of the present invention. Therefore, the rejection should be withdrawn.

Conclusion

As Applicants have addressed and overcome all rejections in the Office Action, Applicants respectfully request that the rejections be withdrawn and that the claims be allowed.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Kecia Reynolds (Reg. No. 47,021) at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

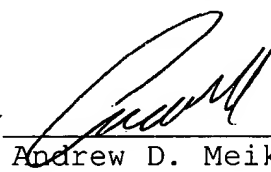
Pursuant to the provisions of 37 C.F.R. § 1.17 and 1.136(a), Applicants hereby petition for an extension of three (3) months to January 19, 2003 for the period in which to file a response to the outstanding Office Action. The required fee of \$930.00 is attached to the Notice of Appeal being filed concurrently herewith.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

BIRCH, STEWART, KOLASCH & BIRCH, LLP

By



Andrew D. Meikle, #32,868

✓
ADM/KJR/jao
0599-0158P

P.O. Box 747
Falls Church, VA 22040-0747
(703) 205-8000